



**DEPARTMENT OF JUSTICE**

**Drug Enforcement Administration**

**[Docket No. DEA-392]**

**Bulk Manufacturer of Controlled Substances Application: Patheon API  
Manufacturing, Inc.**

**ACTION:** Notice of application.

**DATES:** Registered bulk manufacturers of the affected basic classes, and applicants therefore, may file written comments on or objections to the issuance of the proposed registration on or before **[INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]**.

**ADDRESS:** Written comments should be sent to: Drug Enforcement Administration, Attention: DEA Federal Register Representative/DPW, 8701 Morrisette Drive, Springfield, Virginia 22152.

**SUPPLEMENTARY INFORMATION:**

The Attorney General has delegated his authority under the Controlled Substances Act to the Administrator of the Drug Enforcement Administration (DEA), 28 CFR 0.100(b). Authority to exercise all necessary functions with respect to the promulgation and implementation of 21 CFR part 1301, incident to the registration of manufacturers, distributors, dispensers, importers, and exporters of controlled substances (other than final orders in connection with suspension, denial, or revocation of registration) has been redelegated to the Assistant Administrator of the DEA Diversion Control Division (“Assistant Administrator”) pursuant to section 7 of 28 CFR part 0, appendix to subpart R.

In accordance with 21 CFR 1301.33(a), this is notice that on September 26, 2018, Patheon API Manufacturing, Inc., 309 Delaware St., Greenville, South Carolina 29605 applied to be registered as a bulk manufacturer for the basic classes of controlled substances:

<b>Controlled Substance</b>	<b>Drug Code</b>	<b>Schedule</b>
Thebaine	9333	II
Noroxymorphone	9668	II

The company plans to manufacture the above-listed controlled substances as an Active Pharmaceutical Ingredient (API) for supply to its customers.

Dated: November 2, 2018.

**John J. Martin,**

*Assistant Administrator.*